



NOV 14 2001

Stephen Venetianer, Esquire
SmithKline Beecham Corporation
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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,452,808

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,452,808, which claims the human drug product REQUIP® (ropinirole), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of five years.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of December 21, 1998 (63 Fed. Reg. 70411). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,729 - 0) + 627 \\ &= 1,992 \text{ days (5.5 years)}\end{aligned}$$

Since the regulatory review period began on July 14, 1988, after the patent issue date (June 5, 1984), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(B) applies in the present situation because the regulatory review period for the product began after the date of enactment of 35 U.S.C. § 156 (September 24, 1984). Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(B), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,452,808
Granted:	June 5, 1984
Original Expiration Date ¹ :	December 7, 2002

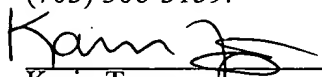
¹Subject to the provisions of 35 U.S.C. § 41(b).

Applicant:	Gregory Gallagher, Jr.
Owner of Record:	SmithKline Beecham Corporation
Title:	4-Aminoalkyl-2(3H)-Indolones
Classification:	424/274
Product Trade Name:	REQUIP® (ropinirole)
Term Extended:	Five years
Expiration Date:	December 7, 2007

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Commissioner for Patents Box Patent Ext. Washington, D.C. 20231	By FAX: (703) 872-9411 Attn: Office of Patent Legal Administration
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Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.


Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc:	David T. Read Acting Director Health Assessment Policy Staff, CDER Food and Drug Administration 1451 Rockville Pike, HFD-7 Rockville, MD 20852	RE: REQUIP (ropinirole) FDA Docket No.: 98E-0478
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